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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tsutomu Okada

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EXAMINER

HUPCZEY, JR, RONALD JAMES

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,814	Applicant(s) OKADA, TSUTOMU	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-10,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27th, 2010 has been entered.
2. Applicant's amendments and arguments, received on May 27th, 2010, have been fully considered by the examiner. Currently, claims 1, 7-10 and 15 and 17-18 are pending with claims 1 and 17 amended and claim 18 newly added. Applicant's submission has obviated the previously filed rejections under both 35 U.S.C. 112 1st and 2nd paragraph and has obviated the previously filed claim objection. The following is a complete response to the May 27th, 2010 communication.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Regarding claim 17, the claim currently reads "a plurality of triangular openings extending outward from the slide hole, an inner end portion of each triangular opening being coupled to the slide hole, wherein a width of each of the plurality of triangular openings is set to become narrower outward from the slide hole such that it cannot be penetrated by the electrode portion" therein. The Examiner has carefully considered this limitation as well as the subject matter of the remainder of the claim in light of the specification. On pages 22-23 of the specification, figures 8A and 8B which depict the claimed embodiment are described. First, the Examiner has failed to find a slide hole in the embodiment of figures 8A and 8B. The specification clearly sets forth on page 22 that "a triangular aperture 43 into which the rod-shaped electrode portion 41 is inserted for advance and retreat is formed in the distal end of a sheath 2. As shown in FIG. 8B, the aperture 43 is a triangular hole in which the rod-shaped electrode portion 41 is inscribed, as showing in FIG. 8B. The other parts of the aperture 43 than that which is occupied by the electrode portion 41 form openings 44, individually". From this recitation it can be seen that there is only a single triangular opening in the distal end of the sheath which, due to the passing of the electrode therethrough, creates three triangular openings in the remaining space not occupied by the electrode. Unlike the embodiment depicted in Figures 7A and 7B, there clearly is not a separate hole (as indicated as slide aperture 18 in figures 7A and 7B) from which additional openings of channels extend therefrom (as indicated by channels 33 in figures 7A and 7B) but rather, a single triangular aperture 43 as set forth on pages 22-23 of the specification.

Additionally, regarding the newly added limitation in claim 17 of "wherein a width of each of the plurality of triangular openings is set to become narrower outward from the slide hole

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such that it cannot be penetrated by the electrode portion", it is noted that such a setting of the width is not, in the Examiner's opinion, supported by the specification. While it can be seen that the triangular aperture 43 in figures 8A and 8B does indeed narrow as the two respective sides reach an intersecting point, the width of these triangular opening is not what is described as set in order to prevent penetration of the electrode into the openings. As presented on page 22 of the specification, "The platelike electrode portion 42 *is adjusted to a size such that cannot penetrate the triangular aperture 43*" (emphasis added). It is clear to the Examiner that the width and/or size of the triangular aperture 43 and hence, the triangular openings 44 are a given, size and then, dependent upon the size of the triangular aperture 43, the electrode portion must be adjusted such that it does not penetrate. The characterization in claim 17 would appear to be the reverse of the actual design of the device. Claim 18 is rejected due to its dependency on claim 17. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. Claims 1 and 7-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (hereinafter "Rexroth")(US Pat. No. 4,943,290).

Regarding claim 1, Kokai discloses a radio knife (electrosurgical device **1**) containing an electrically insulating sheath (insulating flexible tube **2**) having one flow channel inside (see channel in Figure 1), a distal end portion and a proximal end portion, the distal end portion of the sheath having a distal opening (tip opening **13**) and an axis, a support member (stopper member **4**) which closes the distal opening of the sheath (see Figure 4), the support member having a slide hole with a diameter smaller than that of the distal opening extending along the axis thereof

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(see Figures 1 and 4); an operating wire (operation wire **14**) axially moveable in the sheath (see paragraph [0013], lines 4-6), the rod-shaped portion being passed through the slide hole for axial projection and retraction (movement represented by **X**, see Figure 5); a control section (operation part **3**, operation handle **15**) which is provided on the proximal end portion of the sheath (see Figure 5) and controls the operating wire to project and retract the electrode portion in the axial direction (see paragraph [0013], lines 8-14), the control section having a high-frequency current supply portion (see paragraph [0010], lines 6-8) which supplies high-frequency current to the electrode portion (see paragraph [0011], lines 9-12), a liquid feed portion (cock **17**) which is provided on the proximal end side of the sheath and feeds liquid through the one flow channel inside the sheath towards the distal opening (see paragraph [0014]) and an opening for liquid feed which is formed in the support member, the opening being arranged around the slide hole (see paragraph [0014], line 3-5), communicating to the one flow channel (see Figure 1 and paragraph [0014]) and partially blocking flow in the vicinity of the distal end portion (see Figure 1). Kokai fails to disclose the inclusion of a plurality of openings extending outward from the slide hole with an inner portion of each of the straight openings being coupled to the slide hole and is silent in regard to the conductivity properties of the support member.

Rexroth discloses an electrosurgical device (electrosurgical apparatus **10**) containing an electrically insulating sheath (duct means **70**, see col. 9; 3-5) having a distal end portion and proximal end portion, the distal end portion of the sheath having a distal opening and an axis (see Figure 4). Rexroth further discloses the insulation sheath to inherently form a support member which closes the distal opening of the sheath and is insulating. The insulating tip defines a slide hole for the rod-shaped electrode shaft (electrode shaft **50**), the slide hole having a diameter

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smaller than that of the distal opening (see Figure 14). Additionally, Rexroth discloses the device to have a liquid feed portion (input fluid port **18**) and a plurality of straight openings (see openings of channels **75-78** extending in a straight manner into the duct means **70**, Figure 6) for liquid feed (see col. 8; 62 – col. 9; 8) extending outward from the slide hole (opening as in figure 6 extending from electrode shaft **50** outwardly to the inner portion of the means **70**) wherein an inner portion of each of the straight openings is coupled to the slide hole (portion of each of openings of channels **75-78** coupled to electrode shaft **50**) and the plurality of openings are set to a dimension such that each cannot be penetrated by the electrode portion (support walls **80-83** converging to define the openings with channels **75-78** and dimensioned such that electrode shaft **50** cannot penetrate into the opening, see structural relationship in figure 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a plurality of openings such as those disclosed by Rexroth in conjunction with the device disclosed by Kokai to provide an electrosurgical device with a plurality of straight openings extending outwardly from and coupled to the slide hole. As disclosed by Rexroth, it is old and well known to provide a plurality of openings for liquid to flow from in order to create a superior flow pattern to the proximity of the electrode tip. Furthermore, it would have been obvious to provide for an electrically insulative support member as discloses by Rexroth to the device of Kokai to prevent the short circuiting of the device.

Regarding claims 7 and 15, Kokai discloses the sheath to have an extending portion extending ahead of the support member wherein the extending portion has an internal space which stores the electrode portion (see Figure 5).

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Regarding claims 8 and 9, Kokai fails to disclose an extending portion location on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion and for the extending portion to be a hooked bent portion extending substantially at right angles to the distal end portion. Rexroth discloses the electrode portion (electrode shaft **50**) to contain an extending portion (ball tip **26**) located on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion (see Figure 15). Rexroth further discloses the extending portion to be a hooked bent portion (electrode tip **26C**) extending at substantially right angles to the distal end portion (see Figure 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Kokai with the electrode tip designs disclosed by Rexroth in order to catch tissue around the extending portion.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (US Pat. No. 4,943,290) as applied to claim 8 above, and further in view of Kittur et al (US Pat. No. 5,846,241).

Both Kokai and Rexroth fail to disclose the inclusion of a plate-like electrode at the distal end portion. Kittur et al discloses a radio knife (electrocautery device **10**) containing an extending portion (moveable head **22**) in a plate-like arrangement (second electrode **24**) coupled to the distal end of the rod-shaped portion (second wire **20**). Kittur further displays the portion to have a triangular shape (see shape of moveable head **22** in figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plate-like electrode as disclosed by Kittur et al to the joint device of Kokai and Rexroth. All three device disclosed are directed toward the same field of endeavor and the

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utilization of a triangular plate-like electrode would increase the versatility of the device, effectively allowing it to successfully perform a wider variety of treatments.

Response to Arguments

7. Applicant's arguments filed May 27th, 2010 have been fully considered but they are not persuasive.

In response to Applicant's argument that the combination of Kokai in view of Rexroth fails to provide for each of the limitations of amended claim 1, namely the limitation of "a plurality of straight openings extending outward from the slide hole, an inner end portion of each straight opening being coupled to the slide hole, wherein a width of each of the plurality of straight openings is set to a dimension such that it cannot be penetrated by the electrode portion", the Examiner respectfully disagrees. While Applicant correctly states on page 10 of the Remarks that the channels in figure 6 of Rexroth have a plurality of fan-shaped openings indicated as channels 75-78, the Examiner notes that this fan-shape of each channel extends ***radially outward*** from what is being characterized as the slide hole. In the interpretation proffered above of the rejection of claim 1, the limitation of "extending outward from the slide hole" is being interpreted as extending from electrode shaft **50** outwardly to the inner portion of the means **70**. In interpreting the "straight" limitation, the Examiner does not believe that the openings need to radially extend in a straight manner from the slide hole to the inner wall of the sheath 2. In interpreting the claim in this manner, the Examiner is of the position that the limitation of "a plurality of straight openings" is read on by the fan-shaped channels 75-78 of Rexroth extending proximally into the duct means **70** without any bends or curves. While the plurality of channels of Rexroth may not extend radially outward in a substantially straight fashion as intended and

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argued by Applicant, the proffered interpretation and reasoning above meets the broadest reasonable interpretation of the claim afforded to one of ordinary skill in the art.

In response to Applicant's argument that the combination of Kokai in view of Rexroth fails to provide for "a width of each of the plurality of straight openings is set to a dimension such that it cannot be penetrated by the electrode portion", the Examiner respectfully disagrees. While Applicant has stated on page 10 of the Remarks that "the penetration is not prevented by the entire width of the straight openings in FIG. 6 of Rexroth", it is noted that such a limitation requiring the "entire width of the straight opening" to be so formed is not recited in claim 1. It has been held that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In looking at the embodiment depicted in Applicant's figures 7A and 7B in comparison to Rexroth's figure 6, both contain at least one width which prevents the electrode portion from penetrating into the remainder of the opening. While the width of the channels 75-78 of Rexroth gets larger as the radially extend outward from the electrode portion, the claim only requires that a single width of each of the plurality of straight openings prevent the penetration. Therefore, it is at least for this proffered reasoning that the Examiner believes the combination of Kokai in view of Rexroth remains tenable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH